REMARKS

In the December 5, 2003 Office Action, claims 1, 2, 6 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by Drzeniek, et al. (Cancer Letters, 56: 173-179, 1991) or Prall, et al. (The Journal of Histochemistry and Cytochemistry 44: 35-41, 1996). The Office has maintained these rejections in the March 2, 2004 Advisory Action, and as such, applicants have filed herewith a Request for Continued Examination.

To anticipate a claim or render it obvious, a reference must be enabling. This point was recently reaffirmed in an April 7, 2000 decision of the Court of Appeals for the Federal Circuit (CAFC).[1] Citing *In re Paulsen*,[2] the court stated that to be anticipating, a prior art reference must:

1) disclose each and every limitation of the claimed invention;

2) be enabling; and

3) describe the claimed invention sufficiently to place it in possession of a person of ordinary skill in the field of the invention.

Neither Drzeniek, et al. nor Prall, et al. meets this standard.

Applicants' claimed 9 reads as follows:

> 9. A method for reducing angiogenesis in tumor cells, the method comprising; administering a monoclonal anti-CD66a 4D1/C2 antibody in a pharmaceutically compatible carrier to tumor endothelial cells, wherein the monoclonal anti-CD66a 4D1/C2 antibody is in a therapeutically active amount to reduce formation of capillaries in the tumor cells by functionally blocking CD66a on tumor endothelial cell and wherein the antibody was deposited with DSMZ (German-Type Collection of Microorganisms and Cell Cultures) Braunschweig under DSM ACC2371 on October 22, 1998.

Thus the method includes:

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[1] *Helifix Ltd. v. Blok-Lok, Ltd.*, 54 USPQ2d 1299 (Fed. Cir. 2000).
[2] *In re Paulsen*, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994).

1. a monoclonal anti-CD66a 4D1/C2 antibody;
2. a pharmaceutically compatible carrier; and
3. the monoclonal anti-CD66a 4D1/C2 antibody is administered to tumor endothelial cells in a sufficient amount to inhibit formation of capillaries in the tumor by blocking CD66a on tumor endothelial cells.

According to the Office, the claimed antibodies are disclosed in both the Drzeniek, et al. and Prall, et al. references. While the Office speculates that these antibodies would inherently reduce angiogenesis and reduce formation of capillaries, it is the Office's burden to provide evidentiary support of this statement because the references certainly do not provide such support.

As stated above, a reference is not anticipating unless it discloses each and every limitation of the claimed invention, it is enabling, and it described the claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. Applicants submit that one skilled in the art would not realize that the presently claimed composition comprising the claimed antibody would inhibit angiogenesis in tumor cells by blocking CD66a receptors on tumor endothelial cells. Neither reference discusses or describes a method to reduce angiogenesis in **tumor endothelial cells.**

In response to the Office's contention that Drzeniek, et al. and Prall, et al. describe antibodies that would inherently reduce angiogenesis and reduce formation of capillaries, applicants submit that it is well settled as a matter of law, that inherency cannot be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *In re Oelrich*, 212 USPQ 323 (CCPA 1981). Instead, it must consistently occur each and every time, which is necessary under case law to prove inherency. Proving inherency will be very difficult for the Office, especially because the systems set forth in the cited references do not mention or discuss tumor endothelial cells or use of the present antibody therewith. As stated above, Drzeniek, et al. describes binding to a glycoprotein isolated from human bile and there is no discussion that this glycoprotein was expressed by human endothelial cells. The Prall, et al. reference discusses the use of "unknown" antibodies that bind to specific

groups on granulocytes and this binding reduces angiogenesis, however, the reference is completely silent on using the presently claimed antibody for reducing angiogenesis in tumor endothelial cells. Thus, the systems set up in both references could not possible cause the reduction of capillary growth in tumors. Moreover, neither reference is enabling to provide guidance to one skilled in the art to go in the direction of applicants' claimed invention.

Accordingly, applicants respectfully submit that the pending claims are patentably distinguishable over Drzeniek, et al. and Prall, et al. Withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

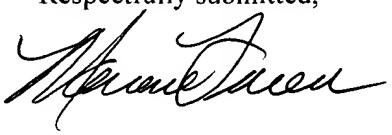
Fee Payable and Petition for Extension of Time.

Applicants hereby petitions for a three (3) month extension of time, extending the deadline for responding to the December 5, 2003 Office Action from March 5, 2004 to June 5, 2004. The entry of this petition results in a petition fee of $475.00. A credit card authorization form in the amount of $860.00 is included herein for payment of the petition fee ($475.00) and RCE fee ($385.00). The U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment, and to credit any excess payment, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Helms reconsider the patentability of claims 1, 2, 6, 8, 9 and 10 in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Helms is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,



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